

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application. No.: 09/825,969
Filed: April 4, 2001
Appellant(s): Thomas D. Doerr
Title: Physician Decision Support System With Improved
Diagnostic Code Capture
Art Unit: 3626
Examiner: Rachel L. Porter
Docket No.: 951130.90029

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant, having filed a timely Notice of Appeal of a Final Office Action in the above-identified patent application, hereby submits this Appeal Brief in support of patentability.

I. REAL PARTY IN INTEREST

The present application is assigned to US-RX, doing business as Wellinx, which is currently doing business as Purkinje, as evidenced by the assignment filed with the USPTO on April 4, 2001, which was recorded April 4, 2001 at Reel/Frame 011725/0371.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-9 and 12-22 are pending in the present application and have been finally rejected under 35 U.S.C. §103(a)..

IV. STATUS OF AMENDMENTS

An amendment was submitted by Appellant after the Final Office Action of October 24, 2006 to cancel claim 11.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a point-of-care decision support system 10. See ¶¶ [0034]-[0037]. The system 10 includes a hand-held terminal 14 usable during examination and providing a display 18 and physician input device 24. *Id.* The system 10 also includes a terminal server 41 communicating with the hand-held terminal and executing a stored program. See ¶¶ [0008] and [0039]-[0044]. When executing the stored program, it is caused to present on the display 18 of the hand-held terminal 14, a navigation menu 44 presenting diagnosis codes representing different medical diagnoses. See ¶¶ [0042], [0043], [0053]-[0055], [0057]-[0061], and [0063]-[0067]. The navigation menu 44 is configured to restrict access to additional support features 46-55 related to a treatment of a medical diagnosis represented by the specific diagnosis code until a diagnosis code is selected. See ¶¶ [0008] and [0009]. Execution of the stored program also causes it to accept from the physician input device 24 of the hand-held terminal 14, a selection identifying a specific diagnosis code from the diagnosis codes and enable access to additional physician support features 46-55 related to a treatment of a medical diagnosis represented by the specific diagnosis code in response to the selection identifying the specific diagnosis code. See ¶¶ [0008], [0009], [0042], [0043], [0053]-[0055], [0057]-[0061], and [0063]-[0067].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the final Office Action of October 24, 2006, claims 1, 4-9, 11, 12, and 14-19 were rejected under 35 U.S.C. § 102(a) as being unpatentable over Evans (U.S. Patent No. 5,924,074), in view of Lewis et al. (U.S. Application No. 2003/0200119 A1). Claims 2 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Lewis et al. in further view of Denny (U.S. Patent No. 6,687,676). Claims 13, 21, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Lewis et al. in further view of Mayaud (U.S. Patent No. 5,845,255). Finally, claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over

Evans and Lewis et al. in further view of Lee ("Fijitsu Pen Computer Will Ship with Windows 95").

VII. ARGUMENT

Claims 1, 4-9, 11, 12, and 14-19 were rejected under 35 U.S.C. § 102(a) as being unpatentable over Evans (U.S. Patent No. 5,924,074), in view of Lewis et al. (U.S. Application No. 2003/0200119 A1).

Regarding the rejection of claim 1, Appellant respectfully disagrees with the asserted interpretation of the art and, furthermore, believes that the proffered rejection is improper. That is, the rejection must be withdrawn because Evans cannot be combined with Lewis et al. in the manner presented in the Office Actions because Evans teaches away from the claimed invention. In fact, Evans teaches directly away from the very proposition for which Lewis et al. was cited. Hence, the rejection is improper and must be withdrawn.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. MPEP § 2142. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case of obviousness, the Examiner must not only show that the combination includes each and every element of the claimed invention, but also provide "a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). That is, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2143.01.

When determining obviousness, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP §2141.02 citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

When considering the reference in its entirety, three criteria must be affirmatively met by the Examiner in proffering the rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143.

Additionally, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP §2143 citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

In the case at hand, Appellant previously showed in the Response of July 13, 2006, that Evans does not teach the present invention. Specifically, Appellant explained that the claims call for a conditional step of enabling access by a physician to additional support features only after a particular diagnosis code has been entered, which distinguishes the claimed invention from the prior art of Evans. In particular, the Examiner noted that Evans, like the present invention, provides a method of inputting diagnosis codes and works at a point of care location. Additionally, as illustrated in Fig. 18 of Evans, it shows that the disclosed system provides access to an optional references database 104 that assists the healthcare provider in prescribing medications and administering treatments. As is apparent from Fig. 20 of Evans, access to the references database 104 is not conditional on the entry of a diagnosis code, as expressly stated in elements (A) and (C) of claim 1. That is, Evans teaches that both the diagnosis codes and the references database are simultaneously available on the same screen and freely selectable in any order desired by the physician. See Fig. 20 and the accompanying description in cols. 11 and 12. The physician is not required to enter a diagnosis code through the left hand side of Fig. 20 in order to unlock access information on related procedures available on the right hand side of Fig. 20. *Id.*

Thus, unlike the claimed invention, the system disclosed by Evans does not use the selection of a diagnosis code to serve as a gate keeper to accessing the

additional information. In fact, Evans, when referring to Fig. 10, states that the physician may access optional practice guidelines that allow the physician to consult resources regarding alternative treatments for various conditions, which are accessible irrespective of the selection of a diagnosis code. See col. 7, ll. 52-61. That is, Fig. 10 clearly shows that this treatment information may be obtained directly from the patient data capture box 140, which does not require the input of diagnosis codes.

This is not a trivial distinction. As discussed with the Examiner during a telephonic interview and addressed in the present application, the present invention recognizes that, by using the diagnosis codes as a gatekeeper to accessing the "additional physician support features," the system is able to encourage physicians to accurately and consistently select diagnosis codes and, in turn, facilitate valuable and extractable data that can be used to enhance outcome-based medicine. That is, the present invention recognizes that by simplifying the entry of diagnosis codes and requiring their entry prior to obtaining desirable information, physicians can be encouraged to specify exact diagnosis codes allowing sophisticated data mining and promoting outcome-based medicine, as described generally in paragraphs [0001]-[0006] and [0013] and elsewhere in the present application.

However, the prior art of record, and, in particular, Evans provides strong evidence that a person of ordinary skill in the art even having access to the required components of: a database, a point of care terminal, diagnosis codes, and physician support materials, would not recognize that the various elements could be linked to incentivize the physicians to capture diagnosis codes or the benefits of doing so. To the contrary, as addressed above, Evans teaches that diagnosis codes should be readily available along side other information. See col. 7, ll. 52-61 and Fig. 20 and the accompanying description in cols. 11 and 12. Evans teaches that diagnosis codes are only optionally presented to the physician, which implies that it is unreasonable to expect the physician to enter the diagnosis code prior to taking advantage of additional features of the inventions.

Therefore, Evans cannot be said to teach or suggest using the selection of a diagnosis code to serve as a gatekeeper to access the additional information. To the contrary, Evans clearly teaches away from the claimed invention. The Office Actions acknowledged the shortcomings of the previous rejection based on Evans but attempted to overcome the shortcomings of the rejection by

modifying/supplementing Evans with Lewis et al. This is clearly impermissible under MPEP §§ 2141.02 and 2145 because a reference cannot be modified in a manner contrary to an express teaching.

As addressed above, Evans expressly teaches that the physician may access optional practice guidelines that allow the physician to consult resources regarding alternative treatments for various conditions, which are accessible irrespective of the selection of a diagnosis code. See col. 7, ll. 52-61. Lewis et al. cannot be used to modify Evans to require diagnosis codes before access to these resources are permitted because Evans expressly teaches away from such a modification by stating that a wide variety of information is readily available along side diagnosis code selection areas in a common screen. Id. Therefore, the present rejection must be withdrawn. MPEP §§ 2141.02 and 2145.

Hence, no basis of rejection remains with respect to claim 1. Accordingly, claims 2-9 and 12-22 are in condition for allowance at least pursuant to the chain of dependency. Nevertheless, as previously addressed before the Examiner, for example, in the Response of July 13, 2006, Appellant respectfully disagrees with the Examiner with respect to the art as applied to claims 2-9 and 12-22 and believes that these claims are additionally distinguishable from the art of record above and beyond the chain of dependency.

Regarding claim 5, which calls for the "additional physician support features" to include "hyperlinks to other physician educational information," the Examiner again cited Evans as teaching the claimed invention. Specifically, the Examiner cited Figs. 14 and 24 and column 13, lines 20-30 of Evans. However, as described by Evans, Fig. 14 merely shows "a logical view of a patient record 220 corresponding to the structure illustrated in Fig. 13." Col. 8, ll. 61-62. On the other hand, Fig. 24 shows a distributed computer network. Evans, when discussing Fig. 24, states that information located at remote locations can be accessed by any of the computing devices shown in Fig. 24 "using a web browser 412... communicating with a Web server" by "having the domain name" (e.g., www.boston.com) associated with the location of the desired data. Col. 13, ll. 27-29. Having and entering a domain name is not tantamount to including hyperlinks to other physician educational information. To the contrary, providing a hyperlink alleviates the need to know/have and enter a specific domain name/address. That is, unlike the system taught by Evans, the claimed invention allows the navigation to linked information from directly within a

given presentation of data/information. For at least these reasons, claim 5 is additionally distinguishable from the art of record.

Claims 2 and 3 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Lewis et al. in further view of Denny (U.S. Patent No. 6,687,676).

As addressed above, Evans does not teach or suggest each and every element of the claims because it does not teach or suggest that access to additional support features is restricted until selection of a diagnosis code is made. Thus, with respect to the primary reference used to support the proffered rejection, the third part of the burden for establishing a *prima facie* case of obviousness has not been met. See MPEP § 2143. Additionally, as addressed above, the proffered combination of Evans and Lewis et al. is improper and cannot be sustained under MPEP §§ 2141.02 and 2145. As will be addressed, the addition of Denny does not remedy either of these shortcomings of the rejection.

Denny teaches a “prescription verification system.” Title of Denny. The section cited by the Examiner states,

After a new prescription has been entered into the host system 12, a printout of the prescription information including the unique code generated by the host system 12 is provided by the printer 46 (FIG. 2) and the printout is presented to the patient, if desired. Thereafter, the health care provider system 14 disconnects from the hosts system 12, such as by terminating the Internet browsing software of the health care provider system 14 as indicated in FIG. 4 by a step 112 and a line 114.

Col. 6, ll. 51-59.

Hence, Denny teaches a computerized system for creating a prescription that allows the prescription data entered into the computer (host) to be printed and, thereby, create a traditional paper copy of the prescription that the patient can then take to a pharmacist. On the other hand, claim 2 calls for the additional physician support features to include “printing of patient handouts about at least one of the diagnosis represented by the specific diagnosis code and the treatment of the medical diagnosis” and claim 3 calls for the additional physician support features to “include printing of a prescription for the treatment of the medical diagnosis.”

First, contrary to the Examiner's assertion, Denny does not teach printing a patient handout about the diagnosis represented by the entered diagnosis code or the treatment of the medical diagnosis. In fact, Denny does not teach or suggest the use of diagnosis codes. Second, when read in conjunction with claim 1, claims 2 and 3 call for providing the ability to print handouts including diagnosis and treatment information or print prescriptions from a hand-held terminal only after the entry of a diagnosis code. Nowhere does Denny teach or suggest providing the ability to create handouts or a printed prescription only after the entry of a diagnosis code.

Appellant does not contend that the printing of a prescription code or patient handouts is new or that diagnosis codes are new. Rather, it is the claimed combination of components, as a whole, that provides a new and non-obvious system, which as described above, is designed to incentivize physicians to consistently and accurately enter diagnosis codes, provide an accurate system for tracking and compiling data, and generally improve medical diagnosis and treatment. However, the Examiner, by picking and choosing features from no less than three different references, has failed to show that the prior art teaches or suggests the claimed combination of elements and functionality. For at least these reasons, claims 2 and 3 are patentably distinct from the art of record.

Claims 13, 21, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Evans and Lewis et al. in further view of Mayaud (U.S. Patent No. 5,845,255).

Regarding claims 13, 21, and 22, the Examiner noted that Mayaud teaches a system that presents a list of prescribed drugs ordered according to frequency of prescription. However, like Evan and Lewis et al., access to these "additional support features" is not predicated on the entry of a diagnosis code. At best, these references teach that diagnosis codes are only optionally presented to the physician. Again, even if a person of ordinary skill in the art were led to combine these references, they still would not teach the elements of claim 13, 21, or 22 when read in light of claim 1. Each of these references teaches away from critical insight of the present invention that through a combination of simplifying the entry of diagnosis codes and requiring their entry prior to obtaining desirable information, that physicians can be encouraged to specify exact diagnosis codes allowing sophisticated data mining promoting outcome based medicine as described

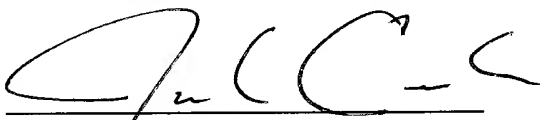
generally in paragraphs [0001]-[0006] of the present application and specifically at paragraph [0013] as well as elsewhere in the application. For at least these reasons, Appellant believes that claims 13, 21, and 22 are patentably distinct from the art of record.

VIII. CONCLUSION

In view of the above, Appellant requests reversal of the final rejection regarding claims 1-21 and a Notice of Allowance.

Respectfully submitted,

Dated: 7/25, 2007

By: 

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APPENDIX A
Claims of Patent Application No. 09/825,969

1. (Previously Presented) A point-of-care decision support system comprising:

a hand-held terminal usable during examination and providing a display and physician input device;

a terminal server communicating with the hand-held terminal and executing a stored program to:

(a) present on the display of the hand-held terminal a navigation menu presenting diagnosis codes representing different medical diagnoses and, wherein the navigation menu is configured to restrict access to additional support features related to a treatment of a medical diagnosis represented by the specific diagnosis code until a diagnosis code is selected;

(b) accept from the physician input device of the hand-held terminal a selection identifying a specific diagnosis code from the diagnosis codes; and

(c) enable access to additional physician support features related to a treatment of a medical diagnosis represented by the specific diagnosis code in response to the selection identifying the specific diagnosis code.

2. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include printing of patient handouts about at least one of the diagnosis represented by the specific diagnosis code and the treatment of the medical diagnosis.

3. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include printing of a prescription for the treatment of the medical diagnosis.

4. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include display of physician educational information about at least one of the diagnosis represented by the specific diagnosis code and treatment of the medical diagnosis.

5. (Previously Presented) The point-of-care decision support system of claim 4 wherein the additional physician support features include hyperlinks to other physician educational information.

6. (Previously Presented) The point-of-care decision support system of claim 1 wherein the terminal server further accepts from the physician input device of the hand-held terminal a selection identifying a specific patient, and wherein the additional physician support features include display of a history of related diagnoses and treatments for the patient.

7. (Previously Presented) The point-of-care decision support system of claim 6 wherein the display of the history of related diagnoses and treatments for the patient includes identification of at least one medication used in the treatment.

8. (Previously Presented) The point-of-care decision support system of claim 1 wherein the diagnosis codes are codes of the international Classification of Diseases developed by the World Health Organization.

9. (Previously Presented) The point-of-care decision support system of claim 1 wherein the selection is a direct selection of a diagnosis code displayed by the navigation menu.

10. (Cancelled).

11. (Cancelled).

12. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include a listing of treatment options for treating an ailment identified by the specific diagnosis code.

13. (Previously Presented) The point-of-care decision support system of claim 12 wherein the listing of treatment options for treating the ailment identified by the specific diagnosis code is sorted in relation to a frequency by which the treatments are used by a physician using the hand-held terminal.

14. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include a listing of specific drugs associated with treating the medical diagnosis represented by the specific diagnosis code.

15. (Previously Presented) The point-of-care decision support system of claim 1 wherein the additional physician support features include a searchable database of drugs.

16. (Previously Presented) The point-of-care decision support system of claim 1 wherein the terminal server and the hand-held terminal provide interfaces connecting to the Internet and wherein the terminal server connects with the hand-held terminal via the Internet.

17. (Previously Presented) The point-of-care decision support system of claim 1 wherein the hand-held terminal provides a wireless link communicating with the terminal server.

18. (Previously Presented) The point-of-care decision support system of claim 1 wherein the physician input device is selected from a keyboard and stylus entry device.

19. (Previously Presented) The point-of-care decision support system of claim 1 wherein the display is a graphic display providing for the display of text and images.

20. (Previously Presented) The point-of-care decision support system of claim 19 wherein display provides a resolution of at least 600 by 200 pixels.

21. (Previously Presented) The point-of-care decision support system of claim 1 wherein the diagnosis codes representing different medical diagnoses are arranged in a list within the navigation menu that is organized based on a frequency of prior use by a particular physician.

22. (Previously Presented) The point-of-care decision support system of claim 1 wherein the diagnosis codes representing different medical diagnoses are arranged in a list within the navigation menu that is organized based on a frequency of their prior use by a predefined group of physicians.

APPENDIX B

EVIDENCE

There is no evidence, other than the documents cited in the final Office Action.

APPENDIX C
RELATED PROCEEDINGS

There are no decisions in related proceedings.

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SUBMISSION OF APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant hereby submits an Appeal Brief in support of the Notice of Appeal filed February 23, 2007, following a final rejection in the above-listed patent application.

The \$250.00 fee for filing an Appeal Brief by a small entity along with the fee for a two month extension and any other fees arising as a result of this or any other communication should be charged to Deposit Account No. 17-0055.

Respectfully submitted,

Dated: 7/25, 2007

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